REMARKS/ARGUMENTS

In response to the Office Action dated February 26, 2008, Applicants have amended the claims which when considered with the following remarks, is deemed to place the present application in condition for allowance. Favorable consideration of all pending claims is respectfully requested.

In order to advance prosecution in this application, claim 12 has been amended to recite "consisting" rather than "comprising."

Claims 12-24 and 26 remain rejected on the ground of nonstatutory obviousness-type double patenting as allegedly unpatentable over claims 1-9 of U.S. Patent No. 6,432,445 in view of U.S. Pat. No. 5,962,019. In the first instance, Applicants note that the Examiner has improperly combined a primary and secondary reference to achieve the instant obvious-type double patenting rejections. As a proper double-patenting rejection is based solely on the claims of a cited reference, no secondary reference may be combined therewith to reject Applicants pending claims.

With respect to the obviousness-type double patenting rejection, the '445 patent claims a capsule comprising cyclosporin, a polyoxyethylene sorbitan fatty acid ester, a reaction product of a natural or hydrogenated castor oil and ethylene glycol, and ethanol. According to the Examiner, component C (a reaction product of a natural or hydrogenated castor oil and ethylene glycol) of the '445 capsule reads on the instant surfactant. The Examiner readily admits that the '445 capsules do not contain the polyethylene glycol of the present claims. Applicants respectfully submit that claims 1-9 of the '445 patent all recite a polyoxyethylene sorbitan fatty acid ester (claims 1-3) and both a polyoxyethylene sorbitan fatty acid ester and a sorbitan fatty acid ester (claims 4-9). In contrast, the presently amended claims do not recite either a polyoxyethylene sorbitan fatty acid ester or a sorbitan fatty acid ester. Looking only at the claims of the

'445 patent in a proper obviousness-type double patenting analysis, it cannot be said that claims 12-24 and 26 as presently amended are obvious variants of claims 1-9 of the '445 patent. Withdrawal of the double patenting rejection is therefore warranted.

Claims 12-24 and 26 have also been rejected on the ground of nonstatutory obviousness-type double patenting as allegedly unpatentable over claims 1-14 of U.S. Patent No. 6,767,555 in view of U.S. Patent No. 5,962,019. Applicants again note that the Examiner has improperly combined a primary and secondary reference to achieve the instant obvious-type double patenting rejections. As a proper double-patenting rejection is based solely on the claims of a cited reference, no secondary reference may be combined therewith to reject Applicants pending claims.

Regarding the double patenting rejection, claims 1-14 of the '555 patent recite a polyoxyethylene sorbitan fatty acid ester and a sorbitan fatty acid ester, in addition to a reaction product of a natural or hydrogenated castor oil and ethylene oxide, and ethanol. In contrast, the presently amended claims do not recite either a polyoxyethylene sorbitan fatty acid ester or a sorbitan fatty acid ester. The Examiner readily admits that the '555 capsules do not contain the polyethylene glycol of the present claims. Looking only at the claims of the '555 patent in making a obviousness-type proper double patenting determination, it cannot be said that claims 12-24 and 26 as presently amended are obvious variants of claims 1-14 of the '555 patent. Withdrawal of the double patenting rejection is therefore respectfully requested.

Claims 12-24 and 26 remain rejected under 35 U.S.C.§ 103(a) as allegedly unpatentable over U.S. Pat. No. 5,342,625 to Hauer et al. in view of U.S. Pat. No. 5,962,019 to Cho et al. Hauer et al. has been cited for allegedly teaching cyclosporin pharmaceutical compositions in the form of micro-emulsion pre-concentrates that are filled in hard gelatin capsules. The formulations include a surfactant such as Cremophor RH 40, described as a reaction product of hydrogenated or natural vegetable oil and

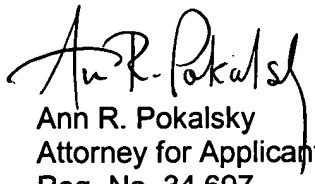
ethylene glycol. Hauer et al. has also been cited for teaching compositions comprising propylene glycol and ethanol, preconcentrate compositions free of water and which form spontaneous emulsions. The Examiner admits that Hauer et al. fail to teach polyethylene glycol in combination with the lower alkanols. Cho has been cited for teaching that polyethylene glycol co-solvents absorb water molecules, which may be present in the formulations, and also impart desirable properties such as viscosity, stability, etc.

It is respectfully submitted that Cho et al. also teach at column 3, lines 62-64: "Also present in the orally acceptable vehicle will be at least one non-ionic polyoxyalkylene surfactant, usually not more than two non-ionic polyoxyalkylene surfactants." Examples of such non-ionic polyoxyalkylene surfactants include polyoxyethylene (4) lauryl ether (BRIJ 30®) and polyoxyethylene (2) mono sorbitan molo-oleate (TWEEN 80®). *See* '019 patent, column 4, lines 14-16. In contrast, as presently amended, claims 12-24 and 26 do not include such a non-ionic polyoxyalkylene surfactant.

In formulating a rejection under 35 U.S.C.§ 103(a), based upon a combination of prior art elements, it remains necessary to identify the reasons why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed. *KSR International v. Teleflex, Inc.,* 82 USPQ 2d 1385 (U.S. 2007). Following *KSR* in the instant case, it remains necessary to identify the reasons why a person of ordinary skill in the art would have chosen to include polyethylene glycol taught by Cho et al., and also chosen to omit a non-ionic polyoxyalkylene surfactant, when Cho et al. specifically teaches such non-ionic polyoxyalkylene surfactant as an essential element. Absent such reasons, the presently claimed invention is not obvious and withdrawal of the rejection of claims 12-24 and 26 under 35 U.S.C. §103(a) is therefore warranted.

Accordingly, in view of the foregoing remarks and amendments, it is respectfully submitted that the present claims are in condition for allowance, which action is earnestly solicited.

Respectfully submitted,



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